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BSI Standards Publication

Dentistry — Endodontic obturating materials

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National foreword

This British Standard is the UK implementation of EN ISO 6877:2021. It is identical to ISO 6877:2021. It supersedes BS EN ISO 6877:2006, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/1, Dental restorative and orthodontic materials.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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English Version

Dentistry - Endodontic obturating materials (ISO 6877:2021)

Médecine bucco-dentaire - Matériaux d'obturation endodontique (ISO 6877:2021)

Zahnheilkunde - Endodontische Obturationswerkstoffe (ISO 6877:2021)

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European foreword

This document (EN ISO 6877:2021) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by March 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 6877:2006.

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Endorsement notice

The text of ISO 6877:2021 has been approved by CEN as EN ISO 6877:2021 without any modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and Restorative Materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 6877:2006), which has been technically revised.

The main changes compared to the previous edition are as follows:

— use of "endodontic" rather than "root canal" for the terminology;

— inclusion of points having a non-uniform taper;

— inclusion of thermoplastic materials not in the form of a point;

— standardization to the use of D, d_3 and d_{16} for measurements of endodontic points at the projection of the tip, 3 mm or 16 mm from the tip of a point;

— harmonization of D, d_3 and d_{16} with the ISO 3630 series;

— reconsidering tests methods;

— addition of ISO 13116 for test method for determining radiopacity of material as a normative reference;

— augmenting the packaging requirements for providing information;

— addition of an annex for measuring the melt-flow rate of thermoplastic materials that are not supplied in point form.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The following information should be taken into account when using this document: specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this document but it is recommended that, for the assessment of such biological risks, reference be made to ISO 7405 and ISO 10993-1. No performance limits are provided in this document for melt mass flow rate, but they might be added in the future.

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INTERNATIONAL STANDARD ISO 6877:2021

Dentistry — Endodontic obturating materials

1 Scope

This document establishes the specifications for the dimensions of various endodontic obturating materials including preformed metal, preformed polymeric-coated metal, polymeric points, thermoplastic obturating material or combinations of the above, suitable for use in the obturation of the root canal system. This document also specifies numerical systems and a colour-coding system for designating the sizes of preformed endodontic obturating points.

Dental endodontic obturating points are marketed sterilized or non-sterilized. This document covers the physical attributes expected of such products as supplied.

Sterility is not included in this document, and any claim that the product is sterile is the responsibility of the manufacturer (see Table 3). Clause 7 specifies the labelling needed, including the instructions for use.

This document does not apply to instruments or apparatus used in conjunction with thermoplastic obturating materials (obturating material that deform with heat). This document is not applicable to materials for support of a coronal restoration.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 3630-1, *Dentistry — Endodontic instruments — Part 1: General requirements*

ISO 13116, *Dentistry — Test method for determining radio-opacity of materials*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 3630-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org

3.1
endodontic obturating material
substance intended as a definitive product to fill a prepared root canal system, usually a combination of *points* (3.2) and *endodontic sealer* (3.15)

3.2
point
preformed metal, preformed polymeric-coated metal, and polymeric cones for use in the obturation of a root canal system

Note 1 to entry: For the purposes of this document, the term "endodontic obturating point (cone)" is abbreviated as "point".

3.3
size designation
numerical indication, "000", of the projected tip diameter, measured in hundredths of a millimetre

3.4
taper
percentage increase in diameter along the length of the *point* (3.2)

EXAMPLE 02 taper represents a 2 % increase in diameter along the length of the point.

3.5
standard point
point (3.2) having a uniform 02 taper over the first 16 mm

3.6
greater taper point
point (3.2) having a uniform taper greater than 02 over the first 16 mm

3.7
variable taper point
point (3.2) which has a taper that varies over the first 16 mm

3.8
auxiliary point
point (3.2) excepting *standard point* (3.5), *greater taper point* (3.6) and *variable taper point* (3.7)

3.9
carrier-based obturating device
point (3.2) designed to obturate a root canal with thermoplastic polymeric material coated on a core material, usually in the shape of a *point* (3.2)

Note 1 to entry: The core material remains in the canal or may be removed after carrying the thermoplastic material.

3.10
injection material
substance supplied in non-conical form, such as pellets for injection after being warmed to a thermoplastic state

3.11
injection system
instrument designed to obturate a root canal with thermoplasticized *injection material* (3.9) using an injection equipment or device

3.12
melt mass-flow rate
MFR
measure of flow through a capillary of a thermoplastic polymer at a particular temperature, measured in grams per unit time at a given force

3.13
unit pack
smallest pack of points distributed, containing one or more sizes of *points* (3.2)

3.14
radiopacity
property of obstructing the passage of radiant energy, such as x-rays, through the representative areas appearing grey or white on the exposed film or sensor image

3.15
endodontic sealer
material intended to permanently seal the root canal dentine from the periapical tissue usually in combination with a solid or semi-solid core material [*endodontic obturating material* (3.1)], to fill voids and to seal root canals during orthograde obturation

4 Requirements

4.1 Appearance

Throughout the tapered length, the point shall be smooth and uniform in appearance, free from extraneous matter. Test according to 6.2.

4.2 Length

Unless otherwise stated by the manufacturer, the overall length shall be not less than 28 mm. Test according to 6.3.

4.3 Size designation and taper

4.3.1 General

The designation shall be in the form of a five-digit numerical set, having two parts: 000 XX, where 000 corresponds to the size designation and XX corresponds to the two significant figures of the taper per cent. For example, a 2 % taper is designated as 02.

The diameter tolerance of points at d_{16} (see Figure 1) shall be:

— ±0,02 mm for metallic points (cones),

— ±0,05 mm for polymeric points or carrier-based obturating devices of sizes 008 to 025,

— ±0,07 mm for polymeric points of carrier-based obturating devices of sizes 030 to 140.

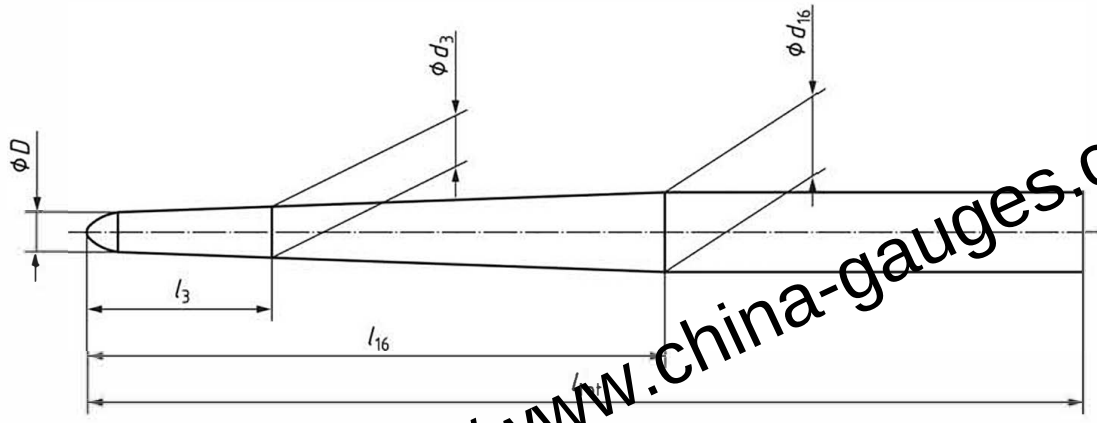
The tolerances of 0,05 and 0,07 are not applicable to *D*.

4.3.2 Standard points

a) The taper of the points shall be uniform for a minimum of 16 mm from the tip (see Figure 1), increasing at 2 % (02) along their length.

b) The size designation of standard polymer points or carrier-based obturating devices shall be in accordance with the numbering system shown in Table 1.

Test according to 6.4.2, and calculate the taper as described in 6.4.3.



Key

D diameter of the projection of the point at the tip

d_3 diameter at 3 mm from tip

d_{16} diameter at 16 mm from tip

l_{tot} total length of the instrument

NOTE 1 The diameters D, d_3 and d_{16} are expressed in millimetres

NOTE 2 Table 1 gives values of D, d_3 and d_{16} for each size of standard points, not carrier-based obturation devices.

NOTE 3 The exact shape of the tip is left to the option of the manufacturer.

Figure 1 — Diagrammatic representation of a point

Table 1 — Size designation for standard points

Dimensions in millimetres

Size designation	D	d_3	d_{16}
008	0,08	0,14	0,40
010	0,10	0,16	0,42
015	0,15	0,21	0,47
020	0,20	0,26	0,52
025	0,25	0,31	0,57
030	0,30	0,36	0,62
035	0,35	0,41	0,67
040	0,40	0,46	0,72
045	0,45	0,51	0,77
050	0,50	0,56	0,82
055	0,55	0,61	0,87
060	0,60	0,66	0,92
070	0,70	0,76	1,02
080	0,80	0,86	1,12
090	0,90	0,96	1,22
100	1,00	1,06	1,32
NOTE The tolerances of 0,05 and 0,07 from 4.3.1 are not applicable to D.			

Size designation	D	d_3	d_{16}
110	1,10	1,16	1,42
120	1,20	1,26	1,52
130	1,30	1,36	1,62
140	1,40	1,46	1,72
NOTE The tolerances of 0,05 and 0,07 from 4.3.1 are not applicable to D.			

4.3.3 Greater taper points

a) The size designation of greater taper polymer points or carrier-based obturating devices shall be in accordance with the numbering system shown in Table 1.

b) The taper of the points shall be uniform for a minimum of 16 mm from the tip (Figure 1), increasing along their length at the taper given by the manufacturer.

Test according to 6.4.2, and calculate the taper as described in 6.4.3.

4.3.4 Variable taper points

The tip diameter and the taper type of the variable taper points shall be designated as variable by the manufacturer (Table 2).

The tolerances of ±0,05 and ±0,07 are not applicable to D.

The colour of variable taper points should be that colour corresponding to the tip size in Table 2.

Test according to 6.4.2.

4.3.5 Auxiliary points

The taper of the auxiliary points is from 02 to 09 (2 % to 9 %).

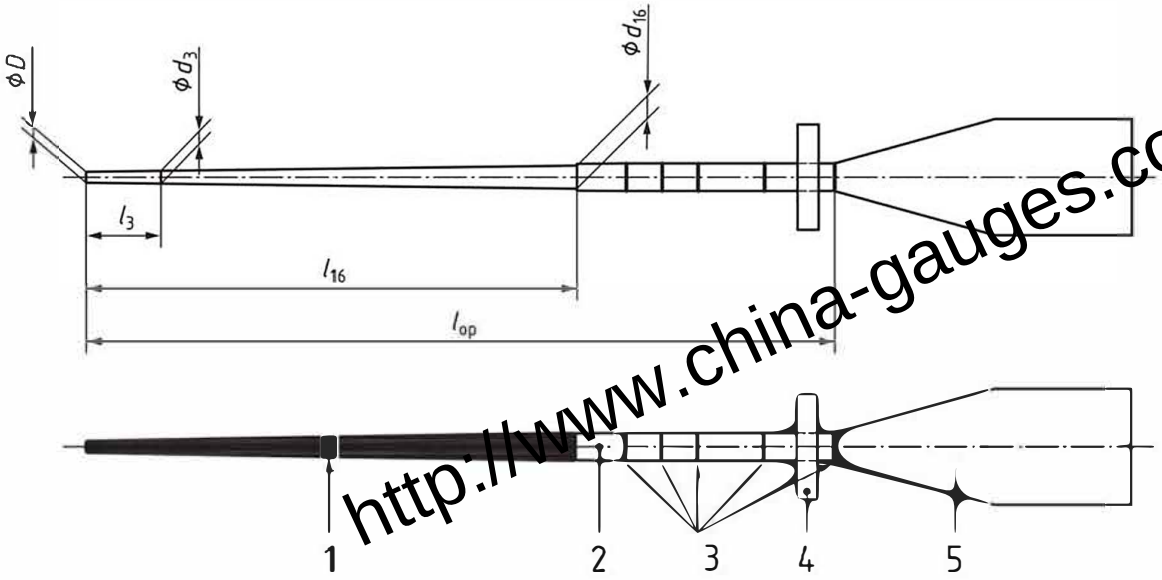
The tip size of the auxiliary points is left to the discretion of the manufacturer.

The colour of auxiliary points should be that colour corresponding to the tip size in Table 2.

4.3.6 Carrier-based obturating material

Figure 2 shows the features of a carrier-based obturating device. If standard, these points shall conform to the dimensional requirements of Table 1.

If variable, the taper of the points is variable over the first 16 mm. The tip diameter and the taper type of the points shall be designated as variable by the manufacturer (see Table 3).



Key

D diameter of the projection of the core at the tip
d_3 diameter of the core at 3 mm from the tip
d_{16} diameter of the core at 16 mm from tip
l_{op} length of the operative part, measured from the tip of the core
1 coating of thermoplastic material (polymeric material)
2 rigid or semi-rigid core
3 calibration marks
4 flexible stop, if provided
5 handle

NOTE 1 The diameters D, d_3 and d_{16} are expressed in hundredths of a millimetre.

NOTE 2 The core is shown at the top and the coated carrier is shown at the bottom.

Figure 2 — Diagrammatic representation of carrier-based obturating devices

4.4 Physical integrity

Samples tested shall not show any sign of fracture (separation), fissures or cracks when tested according to 6.5.

4.5 Radiopacity

The material from which polymeric points are made shall have a radiopacity equivalent to at least 3 mm aluminium.

Test according 6.6 and ISO 13116 using 1 mm thick samples.

4.6 Colour-coding

The use of colour-coding on the packaging or the individual points to indicate the nominal size designation is optional; if used, the colours shall conform to Table 2.

NOTE No colour-code system has been designated for taper.

Table 2 — Colour-coding of points

Size designation	Colour	Abbreviation
010	purple	pur
015	white	wht
020	yellow	yel
025	red	red
030	blue	blu
035	green	grn
040	black	blk
045	white	wht
050	yellow	yel
055	red	red
060	blue	blu
070	green	grn
080	black	blk
090	white	wht
100	yellow	yel
110	red	red
120	blue	blu
130	green	grn
140	black	blk

5 Procurement of samples

Use one or more retail packages from the same batch, containing sufficient material to carry out the specified tests, plus an allowance for repeats, if necessary. Procure at least 20 points or auxiliary obturating material. Procure at least 30 g of injection material for testing in accordance with Annex A.

6 Measurement and test methods

6.1 Test conditions

Conduct all tests at (23 ± 2) °C and a relative humidity of (50 ± 20) %. Condition the points at this temperature and humidity for 1 h prior to testing.

6.2 Visual examination

6.2.1 General

Choose 10 points at random. Carry out visual inspection at normal visual acuity without magnification, unless otherwise specified. Visually examine, without magnification, the points for a smooth and uniform appearance, free from extraneous matter, as specified in 4.1. If all 10 points pass, the product passes. If eight or fewer points pass, the product fails. If nine points pass, test 10 additional points. When 10 additional points are required to be tested, all 10 shall pass for the product to comply.

6.2.2 Labels

References, name of the manufacturer, graphical symbols, lot number and product designation shall be displayed.

When the package is sterile, marked with the symbol for "Sterile" in accordance with ISO 15223-1.

Graphical symbols shall comply with ISO 15223-1.

NOTE Additional information to that specified in Clause 7 can be supplied at the discretion of the manufacturer or as required by regulation.

6.2.3 Instructions for use

Inspect visually to check that requirements specified in Clause 7 have been met. The following information shall be provided:

— general information (name of the manufacturer, product designation),

— indications for use,

— contraindications,

— warnings,

— precautions,

— adverse reactions, and

— step-by-step instructions.

NOTE Additional information to that specified in Clause 7 can be supplied at the discretion of the manufacturer or as required by regulation.

6.3 Length

6.3.1 Apparatus

Visual measurement apparatus shall be used for measuring the length with a minimum accuracy of 0,1 mm.

6.3.2 Method

a) Select 10 points at random of any size and taper.

b) Visually examine the shadow cast by each point using the optical comparator.

c) Measure and record the diameter at lengths d_3 (mm), as defined in Figure 1.

If all 10 points pass, the product passes. If eight or fewer points pass, the product fails. If nine points pass, test 10 additional samples. When 10 additional points are required to be tested, all 10 shall pass for the product to comply.

6.4 Size designation

6.4.1 Apparatus

An optical comparator calibrated to an accuracy of 0,01 mm to measure a polymeric point or a carrier based obturating device.

6.4.2 Method

a) Select 10 points of each size at random. For carrier-based obturating devices, if a solid core is provided, remove the outer layer of thermoplastic material.

b) Visually examine the shadow cast by each point using the optical comparator.

c) Measure and record the diameter at lengths d_3 (mm), as defined in Figure 1.

d) Calculate D using the taper value (T) as calculated in 6.4.3. The taper is the percentage which must be divided by 100 in the formula:

$$D = d_3 - 3T/100$$

e) Tabulate the data for each size of point and compare the values against those in Table 1.

f) Record whether each size of point complies with the requirements of Table 1, including the tolerances in 4.3.1.

NOTE Metallic points can be measured with any type of apparatus if the precision of the apparatus reaches 0,001 mm.

If all 10 points pass, the product passes. If eight or fewer points pass, the product fails. If nine points pass, test 10 additional samples. When 10 additional points are required to be tested, all 10 shall pass for the product to comply.

6.4.3 Taper

a) Select 10 points of each size at random. For carrier-based obturating devices, if a solid core is provided, remove the outer layer of thermoplastic material.

b) Visually examine the shadow cast by each point using the optical comparator. Measure and record the diameter at lengths d_{16} (mm), as defined in Figure 1.

c) Calculate the taper (T) for each of the taper points or carrier cores measured and reported in 6.4.2 using the formula given below:

$$T = 100 \times (d_{16} - d_3)/13$$

d) Tabulate the data for each size of point and compare the values against those in Table 1.

e) Record whether each size of point complies with the requirements of Table 1, including the tolerances in 4.3.1.

If all 10 points pass, the product passes. If eight or fewer points pass, the product fails. If nine points pass, test 10 additional samples. When 10 additional points are required to be tested, all 10 shall pass for the product to comply.

NOTE If a given size fails the size designation requirement (see 6.4.2), taper testing is not required.

6.5 Physical integrity

6.5.1 General

This test may be used for points.

NOTE Carrier-based devices that require heating of the device cannot be tested if the coating sticks to the apparatus. Alternatively, the core material can be tested at room temperature without the coating.

6.5.2 Apparatus

See Figure 3.

6.5.3 Method

Test five randomly selected points of each size using the apparatus in Figure 3 or an equivalent apparatus.

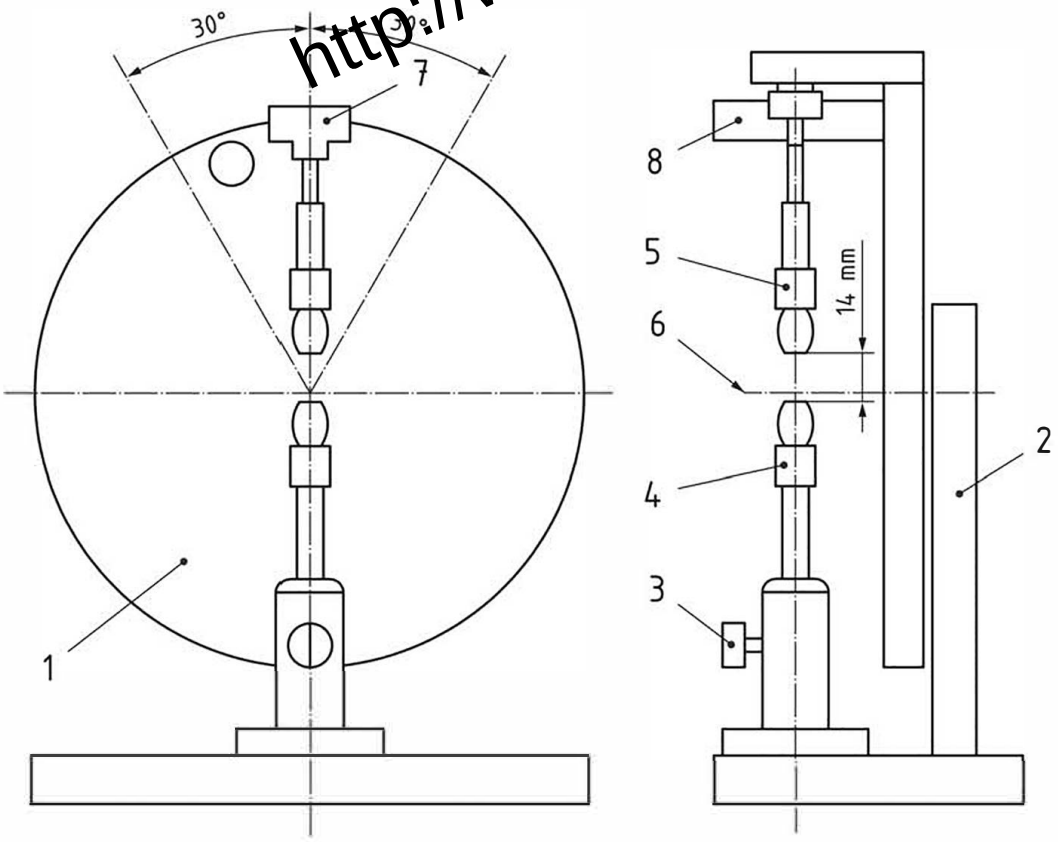
NOTE This test can be performed with standard taper, greater taper or variable taper points.

Grip the first 5 mm of the tip of a point in the stationary pin vice (4 in Figure 3) taking care to minimize damage to the point. Adjust the point so that the junction of the point and the pin vice (4) is at the starting point of the test. Clamp the free end of the point in the moveable pin vice (5) so that the distance between the junctions of the point pin vices (4) and (5) is 14 mm.

Rotate the disc (1) anticlockwise through 30°, then clockwise through 60° and finally return anticlockwise to the starting point of the test. Complete the bending cycle in approximately 2 s. Repeat the bending cycle four times for metallic points and 20 times for polymeric points.

6.5.4 Interpretation of the results

Report whether any of the five points fractured. If none of the five points fracture, the material passes. If one or more or points fracture, the product fails. If one point fractures, test five additional points. None of the five additional points shall fracture for the product to pass.



Key

1 rotating disc
2 bearing support for rotating disc
3 stationary pin vice support with lock
4 stationary pin vice
5 movable pin vice with vertical adjustment
6 centre of rotation
7 suspension point for pin vice (5)
8 handle for disc rotation

Figure 3 — Apparatus for physical integrity testing

6.6 Radiopacity for polymeric points and carrier-based obturating devices

6.6.1 Apparatus

6.6.1.1 Stainless steel ring mould

Mould having an internal diameter of 10 mm and a height of (1,00 ± 0,01) mm.

NOTE A sample can also be made between two glass microscope slides, using 1 mm spacers at the periphery.

6.6.1.2 Covers

Covers made of plastics, glass, paper or other radiolucent material.

6.6.1.3 X-ray apparatus

Use apparatus as specified in ISO 13116.

6.6.1.4 Aluminium step wedge

Use a step wedge conforming to ISO 13116.

6.6.1.5 Other apparatus

Use other apparatus conforming to ISO 13116.

6.6.1.6 Micrometer

Micrometer shall be capable of measuring ±0,01 mm (±10) µm.

6.6.2 Procedure

a) Mould three samples from points, 1 mm ± 0,05 mm thick, using the ring mould. This may be facilitated by heating to mould the point to a uniform thickness.

NOTE For carrier-based obturating devices, the core can be tested separate from the coating, or together. Heat can be applied to mould the sample to a uniform thickness.

b) Determine the thickness of the sample to ±0,01 mm.

c) Irradiate the sample as outlined in ISO 13116.

6.6.3 Interpretation of the results

Treat the results in accordance with Clause 8 of ISO 13116:2014 and determine the radio-opacity (aluminium equivalent) value. If radiographs are recorded on film, refer to ISO 3665.

Calculate the radiopacity in thickness per cent of aluminium, from the thickness of equivalent aluminium in millimetres. Normalize the value of radiopacity by dividing by the measured thickness of the sample. Report the radiopacity to the nearest 0,5 mm of equivalent aluminium. The radio-opacity shall comply with 4.5.

To pass the test, the results of all three determinations shall meet the requirement in 4.5.

6.7 Melt mass flow rate

Test shall be performed for injection material dispensed with an injection system. Refer to Annex A for this test method. The melt mass flow rate shall be stated as described in Annex A.

7 Packaging, marking and instructions and information to be supplied by the manufacturer

7.1 Packaging

The points or thermoplastic material shall be supplied in containers that afford adequate protection and have no adverse effect on the quality of the contents.

NOTE The containers can also be presented in a protective outer pack.

Points shall be packaged in unit packs that protect the contents from damage and, where sterility is claimed (see Table 3), maintain sterility during handling. Unit packs containing more than one size of point shall not permit the various sizes to be readily or unknowingly mixed.

7.2 Labelling

Information shall be clearly marked on the outermost packaging or containers (for multi-dose packs), as appropriate, and as indicated in Table 3.

Instructions shall accompany each package of the material or be otherwise available electronically and shall include the information appropriate to the material as indicated in Table 3.

NOTE 1 Additional information to that specified in Table 3 can be supplied at the discretion of the manufacturer or as required by regulation.

NOTE 2 Table 3 contains optional items and serves as a guide to the manufacturer as to the type of information which might be useful to dentists.

Table 3 — Requirements for marking and instructions for use

	Items of marking and instructions for use	Outermost packaging	Instructions for use
1	The trade name of the product or a means of identification.	M	M
2	The identification or name of the manufacturer.	M	M
3	The address of the manufacturer or the agent responsible for the country of sale. Trademarks or registered mark should be included.	M	M
4	The manufacturer's internet address (URL), if one exists.	M	M
5	The recommended conditions of storage.	M	M
6	Lot identification consisting of a serial number or a combination of letters and numbers that refers to the manufacturer's records for that particular lot of material.	M	NA
7	The expiry date, expressed in accordance with ISO 8601, for the material if stored under the manufacturer's recommended conditions.	M	OPT
8	Graphical symbols in accordance with ISO 15223-1, if applicable.	M	M
9	The presence of hazardous substances in respect of such properties as toxicity, hazard, flammability or tissue irritancy, for both patient and operator, indicated by text or symbol.	OPT	M
10	Identification of the material and the product, for example, trans poly-isoprene (gutta-percha) endodontic points. For endodontic obturating points: size and taper designation (see 4.3), minimum number of points in the unit pack, and nominal length of the points.	M	M
11	Tip diameter of points.	OPT	M
M : mandatory OPT : informative but optional NA : not applicable			

	Items of marking and instructions for use	Outermost packaging	Instructions for use
12	The word "radiopaque" if the material complies with the requirements of 4.5. An explanation of the radiopacity value shall be included. For instance, aluminium has a radiopacity equivalent to that of dentine and may be used for comparison.	OPT	M
13	The word "STERILE", and expiry date if the manufacturer claims that the contents of the unopened pack are sterile. For bulk packs of points marked "STERILE", a statement to the effect that sterility is not guaranteed after the pack is opened. NOTE A claim by the manufacturer that the contents of the unopened pack are sterile is the responsibility of the manufacturer. This document does not specify requirements or test methods for sterility; reference to applicable national regulations can be made. When no national requirements exist, reference may be made to the United States Pharmacopoeia (USP), British Pharmacopoeia (BP) or the European Pharmacopoeia (EP). Standards on methods of validating sterilization processes, produced by ISO/TC 198, *Sterilization of health care products*, are also available: ISO 11137-1, ISO 11137-2, and ISO 11137-3.	M	M, if sterility is claimed, otherwise, NA
14	The net mass or number in each container.	M	OPT
15	The indications for clinical use.	OPT	M
16	Any pharmacologically active ingredients, when present and referred to in the material claim for use.	M	M
17	Date of revision of the instructions.	NA	M
M : mandatory OPT : informative but optional NA : not applicable			

7.3 Declaration of components

The manufacturer shall provide, either in the instructions for use or by means of a safety data sheet, the composition and information on components having hazard potential, present in the material ≥1 % by mass, and any ingredient that is classified as a carcinogen, mutagen or reproductive toxicant (CMR) present in the material ≥0,1 % by mass.

The list shall include a chemical name or its common abbreviation, if available. The chemical abstracts service registry number (CAS number) may be used.

Either the mass per cent range for each listed component or a listing in the order of mass from the highest to the lowest concentration shall be provided.

NOTE CMR is defined by authoritative lists, such as International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), American Conference of Governmental Industrial Hygienists (ACGIH), or EC Annex VI CMR to Regulation (EC) 1272/2008.

Annex A
(normative)

Melt mass-flow rate test

A.1 General

A.1.1 Introduction

The melt mass-flow rate is a "one number" indication of the viscosity of a polymer in the melt phase. The melt mass flow rate is defined as the mass of a thermoplastic polymer in grams, flowing per 10 min, through a capillary of a specific diameter and length. The polymer is under pressure applied with standard weights at one temperature, which must be reported with the flow.

The melt mass-flow rate testing applies to injection material.

A.1.2 Apparatus

A.1.2.1 Plastometer

The plastometer must be calibrated with a standard 2 mm diameter die, as described in ASTM D1238 [19], ISO 1133-1 and ISO 1133-2.

The apparatus for testing is shown in Figure A.1.

A.1.2.2 Scale

The scale must be accurate down to the milligram.

A.1.3 Method

Use a plastometer with a standard die for measuring the melt mass-flow rate. Calibrate all critical apparatus according to the general requirements for the competence of testing and calibration laboratories; see ISO/IEC 17025.

Set the plastometer temperature to between 65 °C and 150 °C and preheat the unit including the piston and chamber. Wait for the unit to reach the temperature.

Separately, warm a 10 g sample and form it into a cylinder, smaller in diameter than the piston diameter. Allow the sample to cool and solidify.

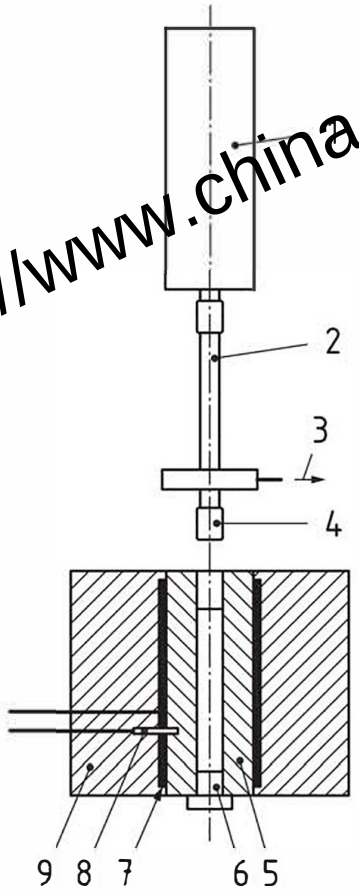
Remove the piston and carefully load the sample into the cylinder chamber. Avoid sticking to the top portion of the cylinder chamber. Insert the piston and let it drop naturally. Allow the sample to be preheated for 1 min to 3 min. Apply the selected load, which may be between 2 kg and 5 kg.

Start the test by initiating the timing device that monitors the pre-heat period, the time that allows the material to soften and begin to melt: (7 ± 0,5) min from the completion of the sample loading. At the end of the pre-heat period and when the top scribe mark on the piston is visible above the cylinder (or top of the guide sleeve) and the lower scribe mark is in the cylinder (or below the top of the guide sleeve), indicating that the piston land is (46 ± 2) mm from the top of the die, reset the timer to zero and simultaneously make the initial cut-off. Discard the extrudate from the pre-heat period. Make the final cut-off exactly when the time interval selected is reached.

Collect and weigh the extruded material at room temperature. If the extruded material contains visible bubbles, discard it and repeat the test. If the initial cut-off was initiated outside of the tolerances of the

pre-heat period or the piston position requirements, discard the specimen and repeat the test with a readjusted piston position after the initial purge, or change the load on the sample.

Once the extruded material is at room temperature, weigh to the nearest milligram. Multiply the weight of the extruded material by a factor to convert it to the flow rate in grams per 10 min.



Key

1 air cylinder
2 piston
3 vacuum device with seal to cylinder
4 piston head
5 cylinder
6 end plug
7 heater
8 temperature sensor
9 insulation

Figure A.1 — Melt mass-flow rate test device

NOTE Depending on the characteristics of the material, the time for which the sample is loaded and the applied temperature can be varied.

For high melt-flow rate materials, the test run time can be 30 s, otherwise less. Calculate the MFR in grams per 10 min and specify the test temperature (°C) load (kg), and test time used in the test. Round off to the nearest 0,1 g.

A.1.4 Interpretation of results

Report the melt mass-flow rate in grams per 10 min, followed by the test temperature, weight applied, and extrusion time.

Report the following:

— the physical form of the material;

— the temperature and the load at which the test was run;

— the details of conditioning, if any;

— any unusual property of the test specimen such as discoloration, sticking, surface irregularity or roughness;

— the melt mass-flow rate, reported as the rate of extrusion in grams per 10 min, followed by the test temperature and load applied.

EXAMPLE If the test ran for 1 min, the temperature was 100 °C, the load was 2,5 kg and the extruded material weighed 0,200 g, then the melt mass-flow rate is reported as '2,0 g/10 min at 100 °C/2,5 kg/1 min'.

— if multiple weights or temperatures are tested, report the melt mass-flow rate at each load and temperature.

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389 Chiswick High Road London W4 4AL UK